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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/787,256 | 05/16/2001 | Jerome Francis Hayes | P32147 | 7589 |

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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

DENTZ, BERNARD I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1625

8

DATE MAILED: 01/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,256

Applicant(s)

HAYES ET AL.

Examiner

Bernard Dentz

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5 and 7</u> . | 6) <input type="checkbox"/> Other: |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al, U.S. Patent 5,776,944 cited by applicants.

It discloses methods for making the instant sesquihydrate compound. It discloses that it is preferred because it is not hygroscopic at from 23 to 64% humidity. See columns 8 and 9. The salutary properties of the methane sulfonate hydrates are disclosed at col. 8, lines 39-43.

The method of making the instant hydrates is disclosed at col. 14, line 48 to col. 15, line 10. Notice that it is disclosed that "the different hydrates may be prepared merely by changing the recrystallization conditions." See col. 15, lines 5-10. This follows immediately the instructions for preparing the methane sulfonic acid salt of which the object compound is the hydrate thereof. These steps are disclosed therein at col. 14, line 48 to col. 15, line 5. They involve mixing the free naphthyridinone compound and methane sulfonic acid. Preferred solvents are CH_2Cl_2 , CHCl_3 , dichloromethane, methanol, ethanol, propanol and water.

The motivation to use mixtures of the solvents (and mixing water with the above lower alkanols meets the instantly recited condition of a solvent comprising water and at least 1 water miscible co-solvent) is the above quoted statement at col. 15, lines 5-10 relating to preparing different hydrates merely by changing recrystallization conditions.

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Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al, same Patent as above, in view of Handanyan et al, WO 96/39406 cited by applicants.

The former is used as above. The latter for a similar naphthyridinone carboxylic acid discloses making a hydrated methane sulfonic acid salt thereof by mixing the reactants in a mixture of water and tetrahydrofuran, a water miscible solvent. Thus one of ordinary skill would have been motivated by the above noted disclosure of Hong et al, particularly col. 15, lines 5-10, and the obvious need to have water present to use a mixture of water with one of the water miscible solvents disclosed by Hong et al. These are the lower alkanols disclosed therein.

Any inquiry concerning this communication should be directed to Bernard Dentz at telephone number 308-4544.

Dentz/LR

January 10, 2002



BERNARD DENTZ
PRIMARY EXAMINER
GROUP 1600